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October 28, 2004

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Mail Stop: Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Appl. No.: 10/633,697; Filed: August 5, 2003

Glycosylation Engineering of Antibodies for Improving Antibody-

Dependent Cellular Cytotoxicity

Inventors:

Pablo UMAÑA et al.

Our Ref:

1975.0010005/TJS/AWL

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Information Disclosure Statement;
- 2. A listing of the cited documents on Form PTO-1449 (50 pages);
- 3. Copies of the cited documents (AL1, AR45 and AS45); and
- 4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents October 28, 2004 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOZOSTEJN & FOX P.L.L.C.

Timothy J. Shea, Jr.

Attorney for Applicants
Registration No. 41,306

TJS/AWL:ddc Enclosures

327657_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Pablo UMAÑA et al.

Appl. No.: 10/633,697

Filed: August 5, 2003

For: Glycosylation Engineering of Antibodies for Improving Antibody-Dependent

Cellular Cytotoxicity

Confirmation No.: 5455

Art Unit: 1636

Examiner: Guzo, David

Atty. Docket: 1975.0010005/TJS/AWL

Information Disclosure Statement

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents AL1, AR45, and AS45 are included.

It is brought to the Examiner's attention that document **AL1**, PCT Patent Publication No. WO 94/11026, has replaced document **AN1**, European Patent Publication No. EP 0 669 836 B1, which was submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(b)(4) in Application No. 09/294,584, filed April 20, 1999.

A copy of documents **AA1** to **AK1** are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003."

Copies of all other documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/294,584, filed April 20, 1999, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached under 37 C.F.R. § 1.98(d).

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter: U.S. Patent Application No. 2004/0072290 A1, Umaña et al., filed May 14, 2003 and cited herewith as document **AK1**; and U.S. Patent Application No. 10/633,699, Umaña et al., filed August 5, 2003 and cited herewith as document **AR45**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

Pablo UMAÑA *et al.* Appl. No. 10/633,697

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Attorney for Applicants Registration No. 41,306

Date: October 28, 2004

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APPLICATION NO. ATTY. DOCKET NO. 10/633,697 1975.0010005/TJS **FORM PTO-1449** FIRST NAMED INVENTOR Umaña et al. INFORMATION DISCLOSURE STATEMENT FILING DATE ART UNIT August 5, 2003 1636 **U.S. PATENT DOCUMENTS EXAMINER** DOCUMENT FILING DATE INITIAL NUMBER DATE NAME **CLASS** SUB-CLASS AA1 4.215.051 07/29/1980 Schroeder et al. 08/29/1979 AB1 4,946,778 08/07/1990 Ladner et al. 01/19/1989 AC1 5,047,335 09/10/1991 Paulson et al. 12/21/1988 AD1 5,547,933 08/20/1996 06/07/1995 Lin 04/07/1998 AE1 5,736,137 Anderson et al. 11/03/1993 AF1 5,776,456 07/07/1998 Anderson et al. 06/07/1995 AG1 5,843,439 12/01/1998 Anderson et al. 06/07/1995 AH1 5,952,203 09/14/1999 Withers et al. 04/11/1997 AI1 5,958,403 09/28/1999 Strom et al. 07/11/1994 AJ1 2003/0175884 A1 09/18/2003 Umaña et al. 08/05/2002 AK1 2004/0072290 A1 04/15/2004 Umaña et al. 05/14/2003 **FOREIGN PATENT DOCUMENTS EXAMINER** DOCUMENT INITIAL NUMBER DATE COUNTRY **CLASS** SUB-CLASS TRANSLATION 05/26/1994 WO 94/11026 WIPO Yes AL₁ No WO 95/24494 09/14/1995 WIPO Yes AM1 No EP 0 669 836 B1 07/03/1996 Europe Yes AN₁ No EP 0 752 248 A1 01/08/1997 Europe Yes AO1 No WO 97/30087 08/21/1997 WIPO Yes AP1 No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Amstutz, H., et al., "Production and Characterization of a Mouse/Human Chimeric Antibody Directed AR 1 Against Human Neuroblastoma," Int. J. Cancer 53:147-152, Wiley-Liss, Inc. (1993) Anderson, W.F., "Human gene therapy," Nature 392:25-30, Nature Pub. Co. (1998) AS 1 Arathoon, W.R., and Birch, J.R., "Large-Scale Cell Culture in Biotechnology," Science 232:1390-1395, AT 1 American Association for the Advancement of Science (1986) EXAMINER DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to Applicant.

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	ATTY. DOCKET NO. 1975.0010005/TJS	APPLICATION NO. 10/633,697
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	AS	10	Dunphy, V Processin	۷.G., and Roth g in the Golgi ،	nman, J.E., "Compartment Apparatus," <i>J. Cell. Bio</i> . 93	ation of Asparagine 7:270-275, Rockefel	-linked Oligosaco ler University Pro	charide ess (1983)
	AT	10	Dunphy, V Oligosacc	V.G., <i>et. al.</i> , "A haride Occurs	attachment of Terminal N-A in Central Cisternae of the	Acetylglucosamine t e Golgi Stack," <i>Cell</i>	o Asparagine-Lir 40:463-472, MIT	iked (1985)
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	AS	11	Dwek, R.A. Association	., "Glycobiology n for the Advan	/: More Functions for Oli cement of Science (199	igosaccharides," <i>Sc</i> 5)	ience 269:1234-1	235, American
	АТ	11	Increased 3	Size of Asparag gene," <i>J. Biol.</i>	ymatic Amplification Invigine-linked Glycans at the Chem. 266:21674-21686	e Surface of NIH 3	Γ3 Cells Expressi	ng the N-ras
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	AR	12	Galactosyll	., and Goldste ransferase," J Biology, Inc. (1	in, I.J., "Ehrlich Ascites Tu . <i>Biol. Chem. 263</i> :3354-33 988)	ımor Cell UDP-Gal: 862, American Socie	N-Acetyl-D-glucety for Biochemi	osamine β(1,4)- stry and
	AS	12	Elion, E.A., Ausubel, F	"Enzymatic N ., <i>et. al</i> ., eds.,	fanipulation of DNA and R John Wiley and Sons, Nev	NA," in <i>Current Pro</i> w York, NY, pp.3.17	tocols in Molecu 7.1-3.17.10 (199	ılar Biology, 8)
	AT	12	Fanger, M.' (1989)	W., <i>et. al.</i> , "Cy	totoxicity mediated by hur	nan Fc receptors fo	r lgG," <i>Immunol</i>	. Today 10:92-9
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	AS	13			Level Expression of a very Expression in COS a				
	AT	13	Frost, J.D., 2 in Children	et. al., "A Pha n with Refracti	se I/IB Trial of Murine M ory Neuroblastoma," Ca	Monoclonal An ancer 80:317-	ti-GD2 A 333, Ame	ntibody 14.G2a erican Cancer S	plus Interleukin- ociety (1997)
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	AR	14	Goldberg, I	D.E., and Korr osaccharide P	nfeld, S., "Evidence for Ext Processing and Lysosomal for Biochemistry and Mole	tensive Subcellular (Enzyme Phosphory	Organization of <i>A</i>	Asparagine- Chem. 258:3159-
	AS	14	their Influer	nce on Glycop	The Oligosaccharides of Gl protein Properties," in <i>Fron</i> iety, Washington, DC, pp.1	itiers in Bioprocessin	Affecting their s	Synthesis and t. al., eds.,
	АТ	14	Gossen, M elements,"	., et. al., "Con TIBTECH 12:	trol of gene activity in high 58-62, Elsevier Science Lt	er eukaryotic cells b td. (1994)	y prokaryotic reç	julatory
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	AR	<u>15</u>	Graham, I vaccine,"	R.A., et. al., "Th Cancer Immun	ne polymorphic epithelial i ol. Immunother. 42:71-80	mucin: potential , Springer-Verla	as an immu g (1996)	nogen for	a cancer
	AS	<u>15</u>	Grierson, Chapters	D., and Covey, 7-9 (1988)	S.N., Plant Molecular Bio	ology, 2nd editio	n, Blackie P	'ublishing,	, London, GB,
	AT	<u>15</u>	Griffiths, C University	6., <i>et. al.</i> , "The Press (1989)	Dynamic Nature of the Go	olgi Complex," J	. Cell Bio. 1	08 :277-2	97, Rockefeller
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	AR	<u>16</u>	Gross, H.J	., et. al., "A Hig	ghly Sensitive Fluorometri onor," <i>Analyt. Biochem. 1</i>	c Assay for	· Sialyltra	nsferase Activity	v Using CMP-9- 1990)
	AS	<u>16</u>	6N-Acetylo	lucosaminyltra	n and Characterization of Insferase (N-Acetylglucos 13:614-619, Tokyo Japane	aminyltran	sferase V) from a Human	lannoside β1- Lung Cancer
	AT	<u>16</u>	Gurley, W. Gene," <i>Mo</i>	B., et. al., "Ups I. Cell. Bio. 6:5	stream Sequences Requir 59-565, American Society	ed for Effic y for Microb	ient Expre	ession of a Soyt 986)	oean Heat Shock
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	AR	17	Haga, Y., and Native	et. al., "Dose-R e Murine Monoc	Related Comparison of Anticlonal Antibody 17-1A," <i>In</i>	itibody-Dependent nt. J. Pancreatol. 1	Cellular Cytotoxio 5:43-50, Humana	city with Chimeric Press Inc. (1994)		
	AS	17	Harpaz, N American	l., and Schachte Society for Biod	er, H., "Control of Glycopr chemistry and Molecular E	rotein Synthesis," , Biology, Inc. (1980	J. Biol. Chem. 25())	5:4894-4902,		
	AT	17	Harvey, D Complex ((1993)	.J., "Quantitative	re Aspects of the Matrix-ases," Rapid Commun. Mass	ssisted Laser Des s Spectrom. 7:614	orption Mass Spe -619, John Wiley	ectrometry of & Sons, Ltd.		
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	AR	18	Hirschberg	g, C.B., and Sn	ider, M.D., "Topography on Rev. Biochem. 56:63-	of Glycosylation in th	e Rough Endop	lasmic Reticulum
	AS	<u>18</u>	Huse, W.E Phage Lar (1989)	D., <i>et. al.</i> , "Gene mbda," <i>Science</i>	eration of a Large Combin 246:1275-1281, America	natorial Library of the	Immunoglobin Advancement	Repertoire in of Science
	АТ	18	Jefferis, R	., et. al., "Reco	gnition sites on human Ig 11-117, Elsevier Science	G for Fcy receptors: B.V. (1995)	the role of glyco	osylation,"
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AR 19 Jenkins, N., and Curling, E.M.A., "Glycosylation of recombinant proteins: Problems and prospects," Enzyme Microb. Technol. 16:354-364, Butterworth-Heinemann (1994) AS 19 Jenkins, N., et. al., "Getting the glycosylation right: Implications for the biotechnology industry," Nat. Biotechnol. 14:975-981, Nature Pub. Co. (1996) AT 19 Köhler, G., and Milstein, C., "Continuous cultures of fused cells secreting antibody of predefined specificity," Nature 256:495-497, Nature Pub. Co. (1975)								dustry," <i>Nat</i> .	
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	AR 20 Kagawa, Y., et. al., "Comparative Study of the Asparagine-linked Sugar Chains of Natural Human Interferon-β1 and Recombinant Human Interferon-β1 Produced by Three Different Mammalian Cells," J Biol. Chem. 263:17508-17515, American Society for Biochemistry and Molecular Biology, Inc. (1988)						mmalian Cells," J.	
	AS	20	Küster, B., et. al., "Sequencing of N-Linked Oligosaccharides Directly from Protein Gels: In-Gel Deglycosylation Followed by Matrix-Assisted Laser Desorption/Ionization Mass Spectrometry and Normal-Phase High-Performance Liquid Chromatography," <i>Analyt. Biochem.</i> 250:82-101, Academ Press (1997)					ometry and
	Koenig, A., "Selectin inhibition: synthesis and evaluation of novel sialylated, sulfated and fucosylated oligosaccharides, including the major capping group of GlyCAM-1," <i>Glycobiology</i> 7:79-93, Oxford University Press (1997)						nd fucosylated -93, Oxford	
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	AR	21	Kolber, M.	A., <i>et. al.</i> , "Me	asurement of cytotoxicity b boxyfluorescein (BCECF),"	y target cell release	and retention o	of the fluorescent Isevier Science
	AS	<u>21</u>	Kornfeld, I 54:631-66	R., and Kornfel 4, Annual Revi	d, S., "Assembly of Aspara ews Inc. (1985)	agine-Linked Oligos	accharides," <i>Ani</i>	n. Rev. Biochem
	AT	21	Kozbor, D Immunol.	., and Roder, J Today 4:72-79	.C., "The production of mo , Elsevier Biomedical Press	noclonal antibodies s (1983)	from human lyn	nphocytes,"
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	AR	22	Lifely, M.R. lines and gr (1995)	, <i>et. al</i> ., "Glycosy own under differ	rlation and biological activity of ent culture conditions," <i>Glycob</i>	CAMPATH- piology 5:813	1H expressed ir -822, Oxford Un	different cell iversity Press
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	AR	23	Lund, J., e Human/Mo Press Ltd.	ouse and Mouse	of IgG/Fc Glycosylation: A e Subclass Immunoglobul	. Comparison of Olig lin Gs," <i>Molec. Immu</i>	osaccharides fr unol. 30:741-748	om Chimeric 3, Pergamon
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	AR	24	Marshall, E Advancem	E., "Gene thera ent of Science	apy's growing pains," <i>Scie</i> (1995)	ence 269:1050-1055,	American Assoc	ciation for the
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	ATTY. DOCKET NO.	APPLICATION NO.
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FORM PTO-1449	FIRST NAMED INVENTOR	
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INFORMATION DISCLOSURE STATEMENT	FILING DATE	ART UNIT
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